JUN 2 5 2014

K140188
p.1 of 10

Submitter and Address of Manufacturing Facility:	Masimo Corporation 40 Parker Irvine, CA 92618 Phone: (949) 297-76 FAX: (949) 297-7592
Date:	May 16, 2014
Contact:	Marguerite Thomlinson Senior Director, Regulatory Affairs
Trade Name:	Masimo Root Monitoring System and Accessories
Common Name:	Patient Monitor
Classification Regulation/ Product Code:	21 CFR 878.2300, Class II/MWI 21 CFR 862.3220, Class II/JKS 21 CFR 868.1400, Class II/CCK 21 CFR 868.2375, Class II/BZQ 21 CFR 870.2700, Class II/DQA 21 CFR 870.2710, Class II/DPZ 21 CFR 882.1320, Class II/GXY 21 CFR 882.1400, Class II/GWQ 21 CFR 882.1400, Class II/OLT 21 CFR 882.1400, Class II/OLW 21 CFR 882.1400, Class II/OMC 21 CFR 882.1400, Class II/ORT
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Device modification and new indications for use
Predicate Devices:	K121013 – Welch Allyn Connex Vital Signs Monitor 6000 Series K110028 – Masimo Radical 7 Pulse CO-oximeter and Accessories K103604 – ISA-Infrared Sidestream Gas Analyzer K051874 – Sedline Sedation Monitor with Frontal PSI and SEDTrace EEG Electrode Set
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

Device Description – Disease/Conditions that Device Diagnose, Treat, Prevent, Cure or Mitigate, Including Patient Population

The Root Monitoring System (Root) is a multifunctional device that monitors vital signs of patients from neonates to adults. Parameters monitored by Root include non-invasive functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), respiratory rate (RRa), inspired/expired gases during anesthesia, recovery and respiratory care, state of the brain by real-time data acquisition and processing of EEG signals, and Patient State Index (PSI) which is an EEG variable that is related to the effect of anesthetic agents.

Explanation of Why Differences in Indication Statement Are Not Critical to Intended Use, and Why Difference Do Not Affect Safety and Effectiveness of Device When Used as Labeled

Root is intended to be used with the previously FDA cleared measurement technologies for the modules of:

- Masimo Radical 7 Pulse CO-Oximeter (Radical 7 module), K110028;
- ISA-Infrared Sidestream Gas Analyzer (ISA module), K103604 and
- Sedline Sedation Monitor with Frontal PSI and SEDTrace EEG Electrode Set (Sedline module), K051874.

Root is intended to be used as an alternative user interface to facilitate access control and monitoring device functions and to connect system networks such as the Patient SafetyNet (K071047).

Device Description – General Description from Labeling, Including Explanation of How Device Functions, Scientific Concepts that Form Basis For the Device

Root displays patient monitoring information from the connected modules. Visual alarms are shown on the Root display and audible alarms are generated through the Root internal speaker. When the module is disconnected from Root, the monitoring information from the module is no longer displayed on Root.

Data from connected modules, including patient monitoring data, can be communicated to network systems. Root also functions as a pass-through means for communicating information between connected devices and network systems.

Subject device and the predicate, Welch Allyn Connex Vital Signs Monitor, K121013 (VSM), are similar in the following manners:

- designed to provide a scalable, modular system that can be configured to address monitoring needs;

- display monitoring information from optional module, including the Masimo Rainbow SET Pulse CO-Oximetry technology (K110028);
- display monitoring information for capnography from optional module.
- communicate with network systems via wired or wireless connection;
- transfer patient monitoring information for supplemental remote viewing and alarming.

The subject device is mainly different from the predicate device in that the subject is connected to the optional ISA module and Sedline module. The predicate is connected to the optional Oridion module, although both the ISA module and Oridion module have capnography monitoring technology. As the result, the indications for use statements for the subject and the predicate device slightly differ, although both the subject and the predicate device are generally intended to provide displays for their respective connected modules.

Device Description – Significant Physical and Performance Characteristics of the Device

The significant physical characteristics for Root include an LCD touchscreen for patient monitoring. The instrument can be powered by AC or by its internal rechargeable battery. The approximate size and weight of the instrument are 11" x 10.5" x 5.5" (27.9 cm x 26.7 cm x 14 cm) and approximately 8 pounds.

The device specifications are shown below for the general functions of the subject device.

FEATURE	**SPECIFICATION**
Display	Color LCD touchscreen
Connected Module	**Parameter**
Radical 7	Parameters per K110028
ISA Module	Parameters per K103604
Sedline Module	Parameters per K051874
General	
Visual/audible alarm	IEC60601-1-8 compliant
Storage/recording	Trend/data storage
Electrical	
AC Power	100-240 volt, 47-63 Hz
Battery	Rechargeable battery
Interface	
Root and Device/Module Connection	Wired/docking interface Wireless interface MOC-9 interface Iris interface Nurse call interface USB interface SD card interface
Network Connectivity	Ethernet Wi-Fi, 802.11 a/b/g; Bluetooth 2.0
Mechanical	
Dimensions	11 x 10.5 x 5.5 inch (27.9 x 26.7 x 14 cm)
Weight	Approximately 8 lbs (3.63 kg)
Environmental	
Operating Temperature	32 to 122°F (0-50°C)

FEATURE	SPECIFICATION
Storage Temperature Humidity	-40 to 158°F (-40 to 70°C), 10-95% non-condensing humidity
Mode of Operation	
Mode of Operation	Continuous

Intended Use

Root serves as a convenient alternative user interface to integrate modules to provide health care professionals the ability to access, control and monitor measurement technologies (within the respective modules) that have been previously cleared by the FDA. Root does not affect the intended use, or alter the indications for use, for the cleared modules with which it is intended to function. Additionally Root is intended to communicate with network systems.

Indications For Use

The Masimo Root Monitoring System is indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments.

The Masimo Root Monitoring System can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station).

The optional Masimo Radical 7 Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical 7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate to multi-parameter devices for the display of those devices.

The optional ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+), intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

ISA CO2: CO_2

ISA AX+: CO_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA OR+: CO_2, O_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing

circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric and infant patients.

The optional SEDLine Sedation Monitor is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

Technological Characteristics

Principle of Operation

Root functions as an alternative user interface that allows access, control and monitoring from the connected modules.

Data from connected modules, including patient monitoring data, can be communicated to network systems. Root also functions as a pass-through means for communicating information between connected devices and network systems.

Mechanism of Action for Achieving the Intended Effect

The system begins functioning when the power is turned on for Root.

Root communicates with connected modules and displays the modules' patient monitoring information on the Root display. The healthcare provider controls the functions of each module using the Root touchscreen display. Visual alarms are shown on the Root display and audible alarms are generated through the Root internal speaker.

By connecting modules or devices to Root, data can be communicated between Root and network systems via wired or wireless connection. Information from network systems can be shown on the Root display for viewing and notification purposes.

Once use is complete, the user then turns the power "off" for Root.

Summary of Technological Characteristics of Subject Device Compared to Predicate Devices

Similarities and Differences between Predicate Device, VSM (K121013) and Subject Device, Root

Subject device and the predicate, Welch Allyn Connex Vital Signs Monitor, K121013 (VSM), are similar in the following manners:

- designed to provide a scalable, modular system that can be configured to address monitoring needs;
- display monitoring information from optional modules, including the Masimo Rainbow SET Pulse CO-Oximetry technology (K110028);
- display monitoring information for capnography from optional module.
- communicate to network systems via wired or wireless connection;
- transfer patient monitoring information for supplemental remote viewing and alarming;

The subject device is mainly different from the predicate device in that the subject is connected to the optional ISA module and Sedline module. The predicate is connected to the optional Oridion module, although both the ISA module and Oridion module have capnography monitoring technology. As the result, the indications for use statements for the subject and the predicate device slightly differ, although both the subject and the predicate device are generally intended to provide displays for their respective connected modules..

Similarities and Differences between Predicate Device, Radical 7 Docked to RDS-1/1B (K110028) and Subject Device, Radical 7 Docked to Root

The main features which are the same for predicate and subject devices are listed below.

- Both have the same fit, form and function for docking the Radical 7.
- Both can recharge the internal battery of the Radical 7 while the Radical 7 is docked.
- Both can operate on AC power or internal battery while the Radical 7 is docked.
- Both can communicate with a network system such as the Patient SafetyNet (K071047) through wired or wireless connection.

The main differences between the predicate and the subject devices are the following.

- The predicate does not have an alternate LCD display. The subject device includes an alternate LCD display to the Radical 7 LCD display.
- For the predicate, the user accesses patient monitoring features by using the Radical 7 LCD display. For the subject device, Root, the user accesses patient monitoring features by using the Root display while the Radical 7 is connected to Root.
- For the predicate, alarms are generated by using the Radical 7 internal speaker and LCD display. For the subject device, visual alarms are shown on the Root display and audible alarms are generated through the Root internal speaker.

Similarities and Differences between Predicate Device, ISA Module Connected to Host Backboard Device (K103604) and Subject Device, ISA Module Connected to Root

The predicate (Host Backboard Device) and the subject (Root) devices are essentially the same in that they function as displays for the ISA module. Both devices display monitoring information from the ISA module. The user performs patient monitoring functions on both predicate (Host Backboard

Device) and subject (Root) devices.

The main difference between the predicate and subject devices is the different interface connections with the ISA module. The predicate device connects to the ISA module through an RS-232 interface. However the subject device connects to the ISA module through the MOC-9 interface.

Similarities and Differences between Predicate Device, Sedline Module Connected to Sedline Monitor (K051874) and Subject Device, Sedline Module Connected to Root

The predicate (Sedline Monitor) and the subject (Root) devices are essentially the same in that they function as displays for the Sedline measurements. Both the predicate and subject devices display monitoring information from the Sedline module. The user performs patient monitoring functions on both predicate and subject devices.

Root differs from the Sedline Monitor in the type of connection between Root and the Sedline module. In this submission, the Sedline module connects to Root through the MOC-9 interface. However in the K051874 filing, the Sedline module connects to the Patient Module Port.

Below is a summary of the monitored parameters and their substantial equivatlence.

TABLE 18

Monitored Parameter	Test Description	Test Objective	Study Endpoints	Results Summary	Conclusion	Substantial Equivalence (SE) Yes/No?
SpO_2, PR, SpCO, SpMet, SpHb and RRa	Display verification	To verify Eagle (Root) user interface	Test personnel began and ended test cases for the Root user interface, and recorded the test results per test procedures.	Pass	Root correctly displayed monitoring information from the connected modules.	Yes SE to K110028
SpO_2, PR, SpCO, SpMet, SpHb, RRa, Breathing Gases, RR, EEG and PSI	Display validation of Radical 7, ISA and Sedline modules	To validate human factors/ usability	Clinicians (users) started and completed the usability test cases and recorded the test results per test procedures.	Pass	Root's ease of use was validated by the clinicians.	Yes SE to K110028, K103604 K051874
SpO_2, PR, SpCO, SpMet, SpHb, RRa, Breathing Gases, RR, EEG and PSI	Display validation	To validate human factors/ usability	Clinicians (users) started and completed the usability test cases and recorded the test results per test procedures.	Pass	Root's ease of use was validated by the clinicians.	Yes SE to K110028, K103604 K051874

TABLE 18						
Monitored Parameter	**Test Description**	**Test Objective**	**Study Endpoints**	**Results Summary**	**Conclusion**	**Substantial Equivalence (SE) Yes/No?**
EEG and PSI	Display verification of Sedline module	To verify Sedline indicator and display	Test personnel began and ended test cases for indictor/display verification, and recorded the test results per test procedures	Pass	Root correctly displayed monitoring information from the Sedline module.	Yes SE to K051874
Breathing Gases and RR	Display verification of ISA module	To verify ISA module indicator and display	Test personnel began and ended test cases for indictor/display verification, and recorded the test results per test procedures	Pass	Root correctly displayed monitoring information from the ISA module.	Yes SE to K103604
N/A. General wireless functions	Wireless interface verification of information from any connected module	To verify the wireless communication between a module fixture and Root	Test personnel began and ended test cases for the wireless interface verification, and recorded the test results per test procedures	Pass	A module fixture wirelessly connected to Root in the similar communication as a wired connection.	Yes SE to K110028
N/A. General docking functions	Docking station function verification	To verify battery management	Test personnel began and ended battery management test cases, and recorded the test results per test procedures.	Pass	Root docking station interfaced correctly with the Radical 7.	Yes SE to K110028
EEG and PSI	MOC-9 interface verification	To verify MOC-9 Port EEPROM	Test personnel began and ended MOC-9 EEPROM verification test cases, and recorded the test results per test procedures	Pass	The MOC-9 interface functioned correctly in EEPROM identification.	Yes SE to K051874
N/A. Breathing gases, RR, EEG and PSI	MOC-9 interface verification	To verify EEPROM Identification for Iris and MOC-9	Test personnel began and ended EEPROM Identification test cases for Iris and MOC-9, and recorded test results per test procedures.	Pass	The MOC-9 and Iris interfaces functioned correctly in EEPROM identification for connected modules.	Yes SE to K103604 K051874
Breathing Gases and RR	Root and ISA module verification	To verify Root/PhaseIn (ISA) capnography module integration	Test personnel began and ended ISA integration test cases, and recorded the test results per test procedures.	Pass	Root correctly displayed monitoring information from the ISA module.	Yes SE to K103604
EEG and PSI	Root and Sedline module verification	To verify Root/Sedline integration	Test personnel began and ended Sedline integration test cases, and recorded the test results per test procedures	Pass	Root correctly displayed monitoring information from the Sedline module.	Yes SE to K051874

TABLE 18						
Monitored Parameter	**Test Description**	**Test Objective**	**Study Endpoints**	**Results Summary**	**Conclusion**	**Substantial Equivalence (SE) Yes/No?**
EEG and PSI	Root and Sedline module verification	To verify Sedline board communication	Test personnel began and ended Sedline board communication test cases, and recorded test results per test procedures	Pass	Root correctly communicated with the Sedline module.	Yes SE to K051874
N/A. General display and speaker functions	Visual/audio alarm verification	To verify visual/audio alarm compliance to IEC 60601-1-8	Test personnel began and ended visual/audio alarm test cases per the IEC standards, and recorded test results.	Pass	Root visual/audio alarms are compliant to IEC60601-1-8.	Yes SE to K110028
SpO_2, PR, SpCO, SpMet, SpHb, RRa, Breathing Gases, RR, EEG and PSI	Visual/audio alarm verification	To verify visual/audio alarm acknowledgment	Test personnel began and ended visual/audio alarm acknowledgment test cases, and recorded the test results per test procedures.	Pass	Root correctly generated visual/audio alarms from the connected modules.	Yes SE to K110028, K103604 K051874
SpO_2, PR, SpCO, SpMet, SpHb, RRa, Breathing Gases, RR, EEG and PSI	Visual/audio alarm verification	To verify audio and visual alarms	Test personnel began and ended audio/visual alarm verification test cases, and recorded test results per test procedures	Pass	Root correctly generated visual/audio alarms from the connected modules.	Yes SE to K110028, K103604 K051874
SpO_2, PR, SpCO, SpMet, SpHb, RRa, Breathing Gases, RR, EEG and PSI	Alarm limit controls verification	To verify alarm limit controls	Test personnel began and ended alarm limit controls verification test cases, and recorded test results per test procedures	Pass	Root correctly generated alarm limits from the connected modules.	Yes SE to K110028, K103604 K051874
N/A. General wired connection	Wired connection verification	To verify Ethernet connection	Test personnel began and ended Ethernet verification test cases, and recorded test results per test procedures	Pass	Root functioned correctly in its connectivity via the Ethernet.	Yes SE to K110028
N/A. General wired connection	Wired connection verification	To verify Iris connectivity to network system	Test personnel began and ended Iris/Patient SafetyNet connectivity test cases, and recorded test results per test procedures	Pass	Root's Iris interface functioned correctly in its connectivity to system networks such as the Patient SafetyNet.	Yes SE to K110028
N/A. General wireless connection	Wireless connection verification	To verify internal radio module	Test personnel began and ended radio module verification test cases, and recorded test results per test procedures.	Pass	Root's internal radio module performed correctly.	Yes SE to K110028

TABLE 18						
Monitored Parameter	**Test Description**	**Test Objective**	**Study Endpoints**	**Results Summary**	**Conclusion**	**Substantial Equivalence (SE) Yes/No?**
N/A. General wireless connection	Wireless connection verification	To verify wireless co-existence per FDA Wireless Guidance	Test personnel began and ended wireless co-existence testing per FDA Guidance, and recorded the test results.	Pass	Root met FDA Wireless Guidance requirements for wireless co-existence testing.	Yes SE to K110028
N/A. General wireless connection	Wireless connection verification	To verify wireless quality of service per FDA Wireless Guidance	Test personnel began and ended wireless quality of service testing verification per FDA Guidance, and recorded test results.	Pass	Root met FDA Wireless Guidance requirements for wireless quality of service testing.	Yes SE to K110028

Non-clinical Testing

See below for the non-clinical testing that was completed.

- Electrical safety testing per IEC60601-1
- EMC testing per IEC60601-1-2
- Alarm testing per IEC60601-1-8
- Usability testing per FDA Human Factors and Usability Draft Guidance
- Wireless testing per FDA Wireless Guidance
- Software verification per FDA Software Guidance
- Mechanical and environmental testing
- Cleaning validation

The results demonstrate that all requirements and performance specifications were satisfied, and that the subject device is substantially equivalent to the predicate device.

Clinical Testing

No clinical testing was done.

Conclusion

It is concluded that the subject device, Masimo Root Monitoring System, is substantially equivalent to its predicates with respect to safety and effectiveness, based on the nonclinical tests discussed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

June 25, 2014

Masimo Corporation
Marguerite Thomlinson
Sr. Director, Regulatory Affairs
40 Parker
Irvine, California, 92618

Re: K140188
Trade/Device Name: Masimo Root Monitoring System
Regulation Number: 21 CFR 878.2300
Regulation Name: Patient Monitor
Regulatory Class: Class II
Product Code: MWI
Dated: May 16, 2014
Received: May 19, 2014

Dear Marguerite Thomlinson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

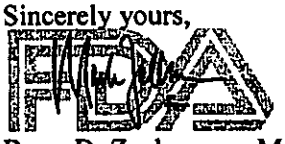
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4. Indications for Use Statement

Indications for Use

510(k) Number: _____

Device Name: Masimo Root Monitoring System

Indications for Use:

The Masimo Root Monitoring System is indicated for use by healthcare professionals for the monitoring of multiple physiological parameters in healthcare environments.

The Masimo Root Monitoring System can transmit data for supplemental remote viewing and alarming (e.g., at a central station).

The optional Masimo Radical 7 Pulse CO-Oximeter and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical 7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate to multi-parameter devices for the display of those devices.

The optional ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+), intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 801 Subpart D)

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Section 4. Indications for Use Statement

ISA CO2: CO_2

ISA AX+: CO_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA OR+: CO_2, O_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane

ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric and infant patients.

The optional SEDLine Sedation Monitor is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 801 Subpart D)

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